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|---|-------------------------------------|------------------------------|----------------------------|--|------------------------|
|  | <b>Sagent Pharmaceuticals, Inc.</b> |                              |                            |  |                        |
|   | <b>Vinorelbine Injection, USP</b>   |                              |                            | <b>Material Safety Data Sheet (MSDS)</b> |                        |
|   | Issue Date:<br><b>Sep 10, 2009</b>  | MSDS No.:<br><b>MSDS 026</b> | Version No.:<br><b>2.0</b> | Form Number:<br><b>R-SOP-009-F001</b>    | Page:<br><b>1 of 8</b> |

### Section 1 - Chemical Product and Company

**Distributor:**

Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Rd, Suite 700  
Schaumburg, IL 60195  
847-908-1600

**Emergency Telephone:** 866-625-1618

**Product Identifier:** Vinorelbine Injection, USP  
**Product Code:** NDC 25021-204-01  
NDC 25021-204-05  
**Common/Trade Name:** Vinorelbine Tartrate Injection (10mg/ mL; 1 mL and 5 mL vials)  
**Chemical Name:** C'-norvincal leukoblastine, 3,4, -didehydro-4-deoxy-, (R-(R\*,R\*))  
-2,3- dihydroxybutanedioate  
**Chemical Family:** Vinca Alkaloid / Cytostatic antineoplastic  
**Product Use:** Pharmaceutical  
**Product Type:** Regulated Prescription Drug  
**Container Information:** Vials

### Section 2 - Composition / Information on Ingredients


| Ingredient           | Weight % | OSHA PEL | ACGGIH TLV | Other Limits Recommended | CAS No.     |
|----------------------|----------|----------|------------|--------------------------|-------------|
| Vinorelbine Tartrate | 1        | None     | None       | 0.5 mcg/m3               | 125317-39-7 |
| Water for Injection  | 99.0     | None     | None       | None                     | 7732-18-5   |

### Section 3 - Hazards Identification

**Primary Physical and Health Hazards:** Vinorelbine Injection, USP is a genotoxic and cytotoxic drug generally used for the first-line treatment of non-small cell lung cancer (NSCLC). Adverse effects from exposure may include blood chemistry changes and effects to digestive and circulatory system. Vinorelbine is fetotoxic and embryotoxic.

**Routes of Entry:** Contact with skin/eyes; inhalation of aerosols or accidental ingestion. Vinorelbine Injection, USP should be with supervision of a physician to control and monitor drug side effects.

**Signs & Symptoms of Exposure:** May cause severe irritation to skin, eyes, and respiratory tract. May cause nausea, vomiting, constipation, diarrhea, alopecia (hair loss), fatigue, shortness of breath, bronchospasm and chest pain. May cause allergic reactions.

|   |                                     |                              |                            |  |                        |
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**Chemical Listed as Carcinogen:** NTP: No IARC: No OSHA: No


**Medical Conditions Generally Aggravated by Exposure:** Pre-existing hypersensitivity to vinorelbine tartrate or other vinca alkaloids. Pre-existing bone marrow, gastrointestinal, nervous system, pulmonary, gonadal, or skin ailments; or pregnancy.

#### Section 4 - First Aid Measures

- Eye Exposure:** Flush eyes with large volumes of water for 15 or more minutes. Get medical attention if irritation or signs of exposure are noted.
- Skin Exposure:** Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get medical attention if irritation or signs of exposure are noted.
- Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately. Never give anything by mouth to an unconscious person.
- Injection:** In cases of accidental injection, wash and disinfect area, get medical attention.
- Inhalation:** If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.
- Notes to Physician:** See patient package insert in shipping carton for complete information.

#### Section 5 - Fire Fighting Measures

- Flash Point** Not established
- Autoignition Temperature:** Not established
- Flammable Limits in Air** Lower %: Not established  
Upper %: Not established
- Flammable Limits:** Not established
- Extinguishing Media** Use water or an ABC multi-purpose extinguisher.

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**Special Fire Fighting Procedures:**

As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is aqueous based and is not expected to present a fire hazard concern.

**Unusual Fire/Explosion Hazards:**

Heat of the fire could cause vials to burst.

**Section 6 - Accidental Release Measures**

**Spill:** Isolate area around the spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the spilled liquid with a suitable material, then clean the affected area with soap and water. Additionally, application of a 50% solution of household bleach (in water) for 10 minutes can be used to further decontaminate the affected spill area. Use care to avoid splashing when applying the bleach solution. Absorb the bleach-treated spill using a suitable material, then clean again with soap and water. Dispose of all spill materials according to the applicable federal, state, or local regulations.


**Release to Air:** If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

**Section 7 - Handling and Storage**

**General Handling:** Vinorelbine tartrate is a cytotoxic anti-neoplastic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic anti-neoplastic agents to minimize potential exposures. Avoid ingestion, inhalation, skin contact, and eye contact. When handling, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this anti-neoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this product.

**Waste Disposal Method:** Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal guidelines.

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**Storage Conditions:** Store the vial under refrigeration at 2° to 8° C (36° to 46° F) in the carton. Protect from light. **DO NOT FREEZE.** Follow instructions provided in packaging.

### Section 8 - Exposure Controls / Personal Protection

Under normal use and handling conditions, no protective equipment is required. The following is recommended for a production setting.

**Respiratory Protection:** Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Eye Protection:** Safety glasses

**Ventilation:** Handle product in a well-ventilated area.


**Skin Protection:** When handling this product, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to this product. Persons known to be allergic to latex rubber should select a nonlatex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.

**Other Protective Equipment:** Lab Coat

**Additional Exposure Precautions:** Wash hands following use. No eating, drinking, or smoking while handling this product.

#### Exposure Limits

| <u>Compound</u>      | <u>Issuer</u> | <u>Type</u> | <u>OEL</u> |
|----------------------|---------------|-------------|------------|
| Vinorelbine tartrate | OSHA          | PEL         | NE         |
|                      | ACGIH         | TLV         | NE         |
|                      | -----         | STEL        | NE         |


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### Section 9 - Physical and Chemical Properties

|                             |                           |                             |                                 |
|-----------------------------|---------------------------|-----------------------------|---------------------------------|
| <b>Physical State:</b>      | Liquid                    | <b>Specific Gravity:</b>    | Not available                   |
| <b>Appearance and Odor:</b> | Clear to pale yellow sol. | <b>Evaporation Rate:</b>    | Approx to water                 |
| <b>Boiling Point:</b>       | Approx 100 <sup>0</sup> C | <b>Solubility in Water:</b> | >1,000 mg/mL in distilled water |
| <b>Vapor Pressure:</b>      | Not available             | <b>pH:</b>                  | 3.5                             |
| <b>Vapor Density:</b>       | Not available             | <b>Molecular Weight:</b>    | 1079.12                         |

### Section 10 - Stability and Reactivity

|  |   |
|--|---|
| <b>Stability:</b>                            | Not determined  |
| <b>Incompatibility (Materials to avoid):</b> | This product is reported to react with strong oxidizing agents and strong bases.  |
| <b>Hazardous Decomposition:</b>              | Decomposition products of this compound may include potentially hazardous byproducts including various oxides of carbon and nitrogen.   |
| <b>Hazardous Polymerization:</b>             | Will not occur  |
| <b>Conditions to Avoid:</b>                  | Heat may cause this product to decompose, destroying the product and producing irritating vapors and toxic gases (e.g., carbon oxides, nitrogen oxides). Avoid contact with incompatible chemicals. |

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## Section 11 - Toxicological Information

### Acute Toxicity

| Component            | Type             | Route           | Species | Dosage               |
|----------------------|------------------|-----------------|---------|----------------------|
| Vinorelbine tartrate | LD <sub>50</sub> | Oral            | Rat     | 26 mg/kg to 34 mg/kg |
| Vinorelbine tartrate | LD <sub>50</sub> | Intravenous     | Rat     | 11 mg/kg to 12 mg/kg |
| Vinorelbine tartrate | LD <sub>50</sub> | Oral            | Mice    | 77 mg/kg to 89 mg/kg |
| Vinorelbine tartrate | LD <sub>50</sub> | Intravenous     | Mice    | 32 mg/kg to 42 mg/kg |
| Vinorelbine tartrate | LD <sub>50</sub> | Intraperitoneal | Mice    | 78 mg/kg             |

Single intravenous doses of 1 or 2 mg/kg were lethal to Beagle dogs.

## Section 12 - Ecological Information

Vinorelbine Tartrate is anticipated to degrade when exposed to sunlight. The photo-degradation half-life is reported as 9.07 hours. Vinorelbine is unlikely to bio-accumulate and has no toxicity to bacteria at environmental concentrations less than 1000 mg/L.

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.


## Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

|   |                                     |                              |                            |  |                        |
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### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

#### **U.S. Regulations**

TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

SARA 313 - *Not on this list*


OSHA Substance Specific - *No*

### Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.  
 1901 N. Roselle Rd, Suite 700  
 Schaumburg, IL 60195  
 847-908-1600

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**Glossary:** This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

|            |   |
|------------|---|
| ACGIH      | American Conference of Governmental Industrial Hygienists                         |
| AIHA       | American Industrial Hygiene Association   |
| CAS Number | Chemical Abstract Service Registry Number   |
| CERCLA     | Comprehensive Environmental Response Compensation and Liability Act (of 1980)     |
| CHAN       | Chemical Hazard Alert Notice  |
| CHEMTREC   | Chemical Transportation Emergency Center  |
| DOT        | Department of Transportation  |
| EPA        | Environmental Protection Agency   |
| HEPA       | High Efficiency Particulate Air (Filter)  |
| IARC       | International Agency for Research on Cancer                                       |
| ICAO/IATA  | International Civil Aviation Organization/International Air Transport Association |
| IMO        | International Maritime Organization   |
| KOW        | Octanol/Water Partition Coefficient   |
| LEL        | Lower Explosive Limit   |
| MSDS       | Material Safety Data Sheet  |
| MSHA       | Mine Safety and Health Administration   |
| NA         | Not Applicable, except in Section 14 where NA = North America                     |
| NE         | Not Established   |
| NADA       | New Animal Drug Application   |
| NAIF       | No Applicable Information Found   |
| NCI        | National Cancer Institute   |
| NIOSH      | National Institute for Occupational Safety and Health                             |
| NOS        | Not Otherwise Specified   |
| NTP        | National Toxicology Program   |
| OSHA       | Occupational Safety and Health Administration                                     |
| OEL        | Occupational Exposure Limit   |
| PEL        | Permissible Exposure Limit (OSHA)   |
| RCRA       | Resource Conservation and Recovery Act  |
| RQ         | Reportable Quantity   |
| RTECS      | Registry of Toxic Effects of Chemical Substances                                  |
| SARA       | Superfund Amendments and Reauthorization Act                                      |
| STEL       | Short Term Exposure Limit   |
| TLV        | Threshold Limit Value (ACGIH)   |
| TPQ        | Threshold Planning Quantity   |
| TSCA       | Toxic Substances Control Act  |
| TWA        | Time Weighted Average/8 Hours Unless Otherwise Noted                              |
| UEL        | Upper Explosive Limit   |
| UN         | United Nations  |
| USP        | United States Pharmacopeia  |
| WEEL       | Workplace Environmental Exposure Level (AIHA)                                     |